PCT / SE 2005 / 000429

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(71) *Sökande* *Åmic AB, Uppsala SE*
Applicant (s)

(21) *Patentansökningsnummer* *0400662-3*
Patent application number

(86) *Ingivningsdatum* *2004-03-24*
Date of filing

Stockholm, 2005-04-05

För Patent- och registreringsverket
For the Patent- and Registration Office

Gunilla Larsson

Avgift
Fee

PATENT- OCH REGISTRERINGSVERKET
SWEDEN

Postadress/Adress
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

Assay device and method

The present invention concerns an assay device or assay system or a component thereof, e.g. for blood analysis, as well as methods of their use, e.g. a method for detecting an analyte in a blood sample, using such device or component.

Background

Analytical and diagnostic determinations are frequently performed on liquid samples, comprising in addition to the analyte of interest, also countless other components, chemical and particulate, which often interfere with the handling of the sample and may influence the quantitative or qualitative determination of the analyte.

For example, numerous clinical diagnostic methods are based on the detection of an analyte in a blood sample. Frequently, such detection is achieved in a disposable assay device, allowing rapid and simple diagnosis. One important application is the wide field of immunology, where analytes are detected with the aid of specific antibodies, capable of binding to the analytes and forming detectable complexes, usually with the aid of ligands aiding the detection.

When performing a test using a blood sample from a patient, many factors need to be considered. Whole blood is prone to clotting, reducing or preventing the desired flow of the sample in the assay device. The red blood cells, even in the absence of clotting, may inhibit or retard flow. Further, red blood cells may inhibit binding between specific binding pair members. Red blood cells also have enzymatic activity, which, depending on the assay employed, may interfere with the signal produced.

Unfortunately, red blood cells present in whole blood also scatter and absorb light thus interfering with assay methodologies which measure either reflected or transmitted light. Other cells may interfere with particular determinations; for example, cholesterol determinations can be effected by cholesterol present in cell membranes.

Consequently many assays involve a step of separating the red blood cells from the plasma, whereupon the assay is carried out on plasma or serum. When the separation is performed before clotting, plasma is obtained. When clotting has occurred before separation, serum is obtained.

The red blood cells can be separated from plasma through centrifugation, which however requires relatively large volume of sample, and the use of a centrifuge. This is also time consuming and constitutes an additional step of handling the sample, which should be avoided when potentially contagious blood-borne pathogens are involved. Further, the risk of the sample being contaminated by the individuals handling it, cross-contaminated by parallel sample or mixed up with other samples is increased.

The most common type of disposable assay device consists of a zone or area for receiving the sample, a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively. These assay devices are known as chromatography assay devices or simply referred to as strip tests. They employ a porous material defining a path for fluid flow capable of supporting capillary flow, e.g. a filter material. The sample-receiving zone frequently consists of a more porous material, capable of absorbing the sample, and, when the separation of blood cells is desired, effective to trap the red blood cells. Examples of such materials are fibrous materials, such as paper, fleece, gel or tissues, comprised e.g. of cellulose, wool, glass fibre, asbestos, synthetic fibres, polymers or mixtures of the same. The transport or incubation zone commonly consists of the same or similar materials, often with another porosity than the sample-receiving zone. Likewise, the reaction zone, which may be integrated with the incubation zone, or constituting the most distal part thereof, commonly consists of similar, absorbing fibrous materials, or any of the above listed materials.

In an assay device or strip test, the porous material (-s) is (are) assembled on a carrier, such as a strip of thermoplastic material, paper, cardboard or the like. Further, a cover can be provided, said cover having at least one aperture for receiving the sample, and an aperture or transparent area for reading the result of the assay.

Nitrocellulose materials are also frequently used as the matrix constituting the transport or reaction zone, connecting the receiving zone and the reaction zone. A significant disadvantage with nitrocellulose is its high non-specific binding of proteins and other bio-molecules. Present test strips however often handle a surplus of sample, reducing the influence of this binding.

Prior art

EP 1 371 984 discloses a chromatographic assay device and method for detecting the presence of an analyte in a sample of whole blood, utilizing a red blood cell separating agent to aggregate red blood cells and permit plasma or serum to flow by capillary action. The carrier material is exemplified as a paper (fibrous), or membranes of cellulose, fibreglass, cloth, both naturally occurring and synthetic, as well as porous gels.

Although frequently used and well known in the art, the above carrier materials are associated with many drawbacks. The structure of the materials will always vary between different batches, and also within the material, due to the random distribution of the fibres e.g. in a fibrous material, or cavities e.g. in a gel-like material. Similarly, the chemical properties of the material, e.g. the distribution of chemicals added to the material, will inevitable vary for the same reasons as above.

WO 03/103835 discloses micro fluidic systems comprising a substrate, and, provided on said substrate, at least one flow path interconnecting with functional means in which liquid samples can be subjected to different desired procedures, said flow path comprising a plurality of micro posts protruding form said substrate.

Summary of the invention

The present invention makes available a device for the detection of an analyte in a liquid sample, or a component of such device, said device comprising a zone for receiving the sample, a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively, on a substrate, wherein said substrate is a non-porous substrate, and wherein at least one of said receiving zone, reaction zone and optional transport or incubation zone consists of an area of projections substantially vertical to said surface, and having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of said liquid sample in said zone is achieved.

The invention also makes available a method of performing a determination of an analyte in a sample, as set forth in the attached claims, hereby incorporated by reference.

The invention also encompasses embodiments of said device and method, as set forth in the description and claims.

Short description of the drawings

The invention will be described in closer detail in the following description, examples, and attached drawings, in which

Fig. 1 shows schematically an embodiment of the present invention, where a drop of sample is added to a substrate having thereon a multitude of projections substantially vertical to said surface, said projections having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of said liquid sample in said zone is achieved. An arrow indicates the direction of flow.

Fig. 2 shows schematically another embodiment of the present invention, where a drop of sample is added to a substrate to an area A1 substantially without projections, bordering to a second area A2, having such projections. Over the area A2 the height (H), diameter (D) and reciprocal spacing (t1, t2) of the projections is varied so, that a gradual filtration effect is achieved, whereas the neighbouring area A3, acts as transport and/or reaction zone.

Fig. 3 shows schematically an embodiment of the present invention, where the sample-receiving zone or area A1 is lowered in relation to the remaining surface of the substrate, and borders to a second area A2, acting as a filter to a third and consecutive areas A3. A1 thus acts as a sink for particulate substances found in the lateral flow In this embodiment, the second area A2 is slightly higher than both the surrounding areas A1 and A3, and the projections on A2 have a height (H), diameter (D) and reciprocal spacing (t1, t2) different from that of the projections on A3.

Description

Definitions

Before the present device and method is described, it is to be understood that this invention is not limited to the particular configurations, method steps, and materials disclosed herein as such configurations, steps and materials may vary somewhat. It is also to be understood that the terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the present invention will be limited only by the appended claims and equivalents thereof.

It must also be noted that, as used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to a reaction mixture containing "a monoclonal antibody" includes a mixture of two or more antibodies.

In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set out herein.

The term "sample" here means a volume of a liquid, solution or suspension, intended to be subjected to qualitative or quantitative determination of any of its properties, such as the presence or absence of a component, the concentration of a component, etc. The sample may be a sample taken from an organism, such as a mammal, preferably a human; or from the biosphere, such as a water sample, or an effluent; or from an technical, chemical or biological process, such as a process of manufacturing, e.g. the production of medicaments, food, feed, or the purification of drinking water or the treatment of waste effluents. The sample may be subjected to qualitative or quantitative determination as such, or after suitable pre-treatment, such as homogenisation, sonication, filtering, sedimentation, centrifugation, heat-treatment etc. Typical samples in the context of the present invention are body fluids such as blood, plasma, serum, lymph, urine, saliva, semen, gastric fluid, sputum, tears etc.; environmental fluids such as surface water, ground water, sludge etc.; and process fluids such as milk, whey, broth, nutrient solutions, cell culture medium, etc. The present invention is applicable to all samples, but preferably to samples of body fluids, and most preferably to whole blood samples.

The determination may be for any purpose, such as diagnostic, environmental, quality control, regulatory, or research purposes. Examples of diagnostic determinations include, but are not limited to, the determination of blood glucose,

The term "analyte" means any substance that is measured quantitatively or qualitatively.

The terms "zone", "area" and "site" are used in the context of this description, examples and claims to define parts of the flow path on a substrate, either in prior art devices or in a device according to the invention.

The term "reaction" is used to define any reaction taking place between components of a sample and at least one reagent or reagents on or in said substrate, or between

two or more components present in said sample. The term "reaction" is in particular used to define the reaction, taking place between an analyte and a reagent as part of the qualitative or quantitative determination of said analyte.

The term "substrate" here means the carrier or matrix to which a sample is added, and on or in which the determination is performed, or where the reaction between analyte and reagent takes place.

The term "chemical functionality" comprises

The term "biological functionality" comprises all biological interactions between a component in a sample and a reagent on the substrate, such as catalysis, binding, internalisation, activation etc.

The term "physical functionality" here comprises functionalities involved in reactions and interactions other than those that are mainly chemical or biological. Examples include diameter, height, shape, cross section, surface topography and surface patterns, the number of projections per unit area, wetting behavior of the surface of said projections, or a combination thereof, and/or other functionalities influencing the flow, retention, adhesion or rejection of components of the sample.

The distinctions between chemical, biological and physical interactions are not always clear, and it is possible that an interaction, such as an interaction between a component in a sample and a reagent on the substrate, involves both chemical, biological and physical elements.

The terms hydrophilic and hydrophobic, as in hydrophilic or hydrophobic compounds, hydrophilic or hydrophobic interactions etc., have the meaning generally understood by a person skilled in the art, and corresponding to that used in generally recognised textbooks.

Description of preferred embodiments

The present invention makes available a device for the detection of an analyte in a liquid sample, said device comprising a zone for receiving the sample, a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively, on a substrate, wherein said substrate is a non-porous substrate, and said reaction zone and optional transport or incubation zone consist of areas of projections substantially vertical to said surface, and having a height (H),

diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of said liquid sample in said zones is achieved.

Further, a filtering zone may be provided adjacent to the zone for receiving the sample, said filtering zone having projections substantially vertical to its surface, having a height (H), diameter (D) and reciprocal spacing (t1, t2) forming a gradient with regard to the diameter (D) and/or reciprocal spacing (t1, t2) such that components of the sample are gradually retained.

The device according to the invention is advantageously used in analytical applications where the liquid sample contains particulate matter, such as cells, tissue debris, organic or inorganic matter, other contamination etc, which is desired to separate from the bulk of the sample. One important application is when the liquid sample is whole blood and in such cases, the lateral capillary flow involves the separation of red blood cells from plasma without significant rupture of said cells. According to one embodiment, such separation in general, and in particular the gentle separation of red blood cells, is achieved in a gradient of projections wherein the spacing (t1, t2) decreases from about 7 μm to about 1 μm over the length of said filtering zone.

According to one embodiment said receiving zone forms a basin for components separated from the lateral flow, e.g. particulate matter or cells prevented from passing between the projections, or entering that space only to a limited degree.

According to another embodiment the particulate matter travels with the lateral flow. In applications where said liquid sample is whole blood, it is important that said lateral capillary flow involves the transportation of red blood cells without significant rupture of said cells. This is achieved by the present invention through the control of one or more of the parameters of the projections, such as the height (H), diameter (D) and reciprocal spacing (t1, t2), as well as the chemical or biochemical derivatisation of the projections.

The spacing (t1, t2) between said projections can be varied depending on the intended use and the properties of the liquid sample, as well as the properties of components to be separated or transported, and preferably is in the interval of 1 to 100 μm, more preferably in the interval of 1 to 50 μm. The distance between said projections can be chosen by a skilled person, considering which sample the device

is intended for, the properties of said sample, and the properties of the components that are to be separated.

The device according to the present invention is built on a plastic substrate, preferably thermoplastic, or a substrate having a plastic upper layer. This can in turn be coated or derivatised, e.g. using techniques such as sputtering, vapour deposition and the like, and given a coating of silicon, a metal or other. The present invention can also be made of silicon substrates. According to a preferred embodiment the substrate is given a hydrophilic treatment or coating, e.g. by subjecting the substrate to an oxidative treatment, such as e.g. gas plasma treatment, coating with a hydrophilic substance such as silicon oxide, hydrophilic polymers such as dextran, polyethylene glycol, heparin and derivatives thereof, detergents, biologic substances such as polymers, etc.

Consequently, according to one embodiment of the invention, said projections or at least a sub-set thereof are provided with a chemical, biologic or physical functionality. The projections may have chemically reactive groups on their surface. The projections may also have substances with biological affinity bound to their surface.

According to another embodiment, the projections carry structures or groups chosen among hydrophilic groups, hydrophobic groups, positively and/or negatively charged groups, silicon oxide, carbohydrates, amino acids, nucleic acids, and macromolecules, or combinations thereof.

According to yet another embodiment, the projections have a physical property selected from the projection diameter (D), height (H), reciprocal spacing (t1, t2), shape, cross section, surface coating, the number of projections per unit area, wetting behavior of the surface of said projections, or a combination thereof, according to the desired end use of the substrate.

According to another embodiment, particles are provided chemically or physically bound to the substrate, or mechanically trapped within a region comprising a plurality of projections... Said particles are chosen among commercially available particles, so called beads, and may have a core of glass, metal or polymer, or a combination of these, and they optionally carry on their surface chemical or biological moieties, such as polyclonal antibodies, monoclonal antibodies, amino acids, nucleic acids, carbohydrates or combinations thereof.

The present invention also makes available a device suitable for use in or together with a device for detection of an analyte in a liquid sample, wherein said device has projections substantially vertical to its surface, said projections having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that said device is capable of separating components of said liquid sample while achieving a lateral flow of said liquid sample. This device may have one or more of the properties and functionalities described above, depending on its intended use.

This device may be used separately, in association with, or integrated in a device for the analysis of a liquid sample. This device may function as a pre-treatment step in or before a conventional analysis.

The present invention also makes available a method for performing an assay on a liquid sample, said sample being applied to a substrate having a zone for receiving the sample, which is in fluid connection with a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively, wherein said substrate is a non-porous substrate, and said receiving zone, reaction zone and optional transport or incubation zone consist of areas of projections substantially vertical to said surface, and having a height (H), diameter (D)and reciprocal spacing (t1,t2) such, that lateral capillary flow of said liquid sample in said zone is achieved.

According to one embodiment of this method, a filtering step is performed following the addition of the sample, said filtering effected in a filtering zone by projections substantially vertical to the surface of said substrate, the projections having a height (H), diameter (D) and reciprocal spacing (t1, t2) forming a gradient with regard to the diameter (D) and/or reciprocal spacing (t1, t2) such that components of the sample are gradually retained.

This method can be used for all applications where components of a liquid sample need to be separated from the bulk of the sample. The method is however particularly suitable for applications where said liquid sample is whole blood and said lateral capillary flow involves the separation of red blood cells from plasma without significant rupture of said cells.

One way to achieve a gentle separation of components of the sample, is to subject the sample to a filtering zone where the spacing (t1, t2) between the projections

gradually decreases. In applications where the lateral capillary flow involves the separation of red blood cells from plasma, it is important that this takes place without significant rupture of said red blood cells. Ito achieve this, in applications involving the separation of red blood cells, the spacing (t1, t2) preferably decreases from about 7 μm to about 1 μm over the length of said filtering zone.

According to one embodiment of the method, components separated from the lateral flow are retained in a basin, substantially prevented from entering the filtering zone.

Another embodiment, in applications where said liquid sample is whole blood, is a method of achieving a lateral capillary flow involving the transportation of red blood cells without significant rupture of said cells. And if needed a flow of buffer liquid can be used to reduce the amount of cells in the reaction zone, promoting the detection step.

The invention also makes available a method for performing an assay on a liquid sample, in particular a sample of whole blood, wherein said sample is added to a device as described above.

The device according to the present invention surprisingly replaces prior art devices where the substrate, and/or one or more of said zones were made of a porous material such as nitrocellulose, cellulose, asbestos fibres, glass fibres and the like.

A general embodiment is illustrated in Fig. 1, showing a part of a device where the surface of a substrate is covered by projections substantially vertical to said surface, and having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow is achieved.

Another embodiment is illustrated in Fig. 2, showing a part of a device where the sample-receiving area A1 does not have projections on its surface, but where the adjacent area A2 has projections forming a gradient, and the subsequent area A3 functioning as incubating and/or reaction zone. The distance between individual projections in A2 can be different in different areas or zones on the device, the projections having gradually or step-wise narrowing space between them.

According to one particular embodiment for the separation of components from a liquid sample, e.g. red blood cells from plasma, said device has a depression surrounded on at least part of its circumference by projections, the distance (t1, t2) between said projections, as well as their diameter (D), height (H) and shape, being

chosen so, that when a sample of whole blood is added to said depression, the red blood cells are prevented from leaving the depression by the projections down stream of said depression, whereas the plasma will flow through or between said projections.

This embodiment is illustrated in Fig. 3, where the sample-receiving area A1 is lower in relation to the surrounding areas, has no projections on its surface, and borders to an area A2, raised in relation to A1 and the neighbouring area A3, acting as a threshold between these. The raised area A2 has projections substantially vertical to its surface, and having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of the sample is achieved, simultaneously as components of the sample are prevented from leaving A1. This way A1 acts a basin for components separated from the sample, e.g. red blood cells.

The three above embodiments may also be combined, e.g. in an embodiment where a depressed area borders to a raised area, or an area in level with the remaining surface of the substrate, of raised above said surface, and where the projections are placed on the border between said depressed and raised areas, the distance between said posts, as well as their width, height and shape, being chosen so, that when a sample of whole blood is added to said depression, the red blood cells are prevented from leaving the depression, whereas the plasma will flow through said posts.

Advantages of the invention

An advantage of the device according to the invention is the increased speed of the determination, as no separation of cellular material is necessary, or when such separation is desired, rapid separation takes place.

Another advantage of the device is that, due to the open, regular structure and the defined properties of the capillary flow zones, the addition of reagents these zones or the derivatisation of the surface of the projections is greatly simplified.

Yet another advantage of the device is the uniformity of the structure not only within a single device, but also between all devices produced. This result in significantly increased reliability and repeatability of the assays built on the inventive device.

An important advantage of the inventive device is that the degree of separation, from none to total, of the blood cells, can be accurately controlled.

The inventive device has many advantages with respect to the manufacturing process. All capillary zones can be made in one step and no assembly of parts is required. Optionally, a cover having at least one aperture for sample addition and one reading the result of the assay can be placed over the substrate and the capillary zones.

Although the invention has been described with regard to its preferred embodiments, which constitute the best mode presently known to the inventors, it should be understood that various changes and modifications as would be obvious to one having the ordinary skill in this art may be made without departing from the scope of the invention which is set forth in the claims appended hereto.

Claims

1. A device for detection of an analyte in a liquid sample, said device comprising a zone for receiving the sample, a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively, on a substrate, **characterized** in that said substrate is a non-porous substrate, and said reaction zone and optional transport or incubation zone consist of areas of projections substantially vertical to said surface, and having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of said liquid sample in said zones is achieved.

2. The device according to claim 1, wherein a filtering zone is provided adjacent to the zone for receiving the sample, said filtering zone having projections substantially vertical to its surface, having a height (H), diameter (D) and reciprocal spacing (t1, t2) forming a gradient with regard to the diameter (D) and/or reciprocal spacing (t1, t2) such that components of the sample are gradually retained.

3. The device according to claim 1 or 2, wherein said liquid sample is whole blood and said lateral capillary flow involves the separation of red blood cells from plasma without significant rupture of said cells.

4. The device according to claim 3, wherein the spacing (t1, t2) decreases from about 7 μm to about 1 μm over the length of said filtering zone.

5. The device according to claim 2 or 3, wherein said receiving zone forms a basin for components separated from the lateral flow.

6. The device according to claim 1, wherein said liquid sample is whole blood and said lateral capillary flow involves the transportation of red blood cells without significant rupture of said cells.

7. The device according to claim 1, wherein said substrate is a plastic substrate, preferably a thermoplastic substrate.

8. The device according to claim 1, wherein said substrate is a silicon or glass substrate.

9. The device according to claim 1, wherein the spacing (t1, t2) between said projections is in the interval of 1 to 100 μm.

10. The device according to claim 1, wherein said projections or at least a sub-set thereof are provided with a chemical, biologic or physical functionality.

11. The device according to claim 10, wherein the projections have chemically reactive groups on their surface.

12. The device according to claim 10, wherein the projections have substances with biological affinity bound to their surface.

13. The device according to claim 10, wherein the projections carry structures or groups chosen among hydrophilic groups, hydrophobic groups, positively and/or negatively charged groups, silicon oxide, carbohydrates, amino acids, and macromolecules, or combinations thereof.

14. The device according to claim 9, wherein said physical property is selected from the projection diameter (D), height (H), shape, cross section, surface coating, the number of projections per unit area, wetting behavior of the surface of said projections, or a combination thereof.

15. The device according to any one of the preceding claims, wherein particles are provided chemically or physically bound to the substrate, or mechanically trapped within a region comprising a plurality of projections.

16. The device according to claim 15, wherein said particles are chosen among glass, polymers, metals or combinations thereof.

17. The device according to claim 15 or 16 wherein said particles have bound to its surface substances with biological or chemical affinity.

18. A device suitable for use in or with a device for detection of an analyte in a liquid sample, **characterized** in that said device has projections substantially vertical to its surface, said projections having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that said device is capable of separating components of said liquid sample while achieving a lateral flow of said liquid sample.

19. A method for performing an assay on a liquid sample, said sample being applied to a substrate having a zone for receiving the sample, which is in fluid connection with a reaction zone, and optionally a transport or incubation zone connecting the receiving and reaction zone, respectively, **characterized** in that said substrate is a non-porous substrate, and said receiving zone, reaction zone and

optional transport or incubation zone consist of areas of projections substantially vertical to said surface, and having a height (H), diameter (D) and reciprocal spacing (t1,t2) such, that lateral capillary flow of said liquid sample in said zone is achieved.

20. The method according to claim 19, wherein a filtering step is performed following the addition of the sample, said filtering effected in a filtering zone by projections substantially vertical to the surface of said substrate, the projections having a height (H), diameter (D) and reciprocal spacing (t1, t2) forming a gradient with regard to the diameter (D) and/or reciprocal spacing (t1, t2) such that components of the sample are gradually retained.

21. The method according to claim 19 or 20, wherein said liquid sample is whole blood and said lateral capillary flow involves the separation of red blood cells from plasma without significant rupture of said cells.

22. The method according to claims 20 and 21, wherein the spacing (t1, t2) decreases from about 7 μm to about 1 μm over the length of said filtering zone.

23. The method according to claim 20 or 21, wherein components separated from the lateral flow are contained in a basin, substantially prevented from entering the filtering zone.

24. The method according to claim 19, wherein said liquid sample is whole blood and said lateral capillary flow involves the transportation of red blood cells without significant rupture of said cells.

25. The method according to claim 19, wherein said sample is a sample of whole blood and said lateral capillary flow involves the separation of red blood cells from plasma without significant rupture of said red blood cells.

26. A method for performing an assay on a sample of whole blood, **characterized** in that said sample is added to a device according to any one of the preceding claims.

Abstract

A device for detection of an analyte in a liquid sample, or a component of such device, said device or component comprising a zone for receiving the sample, and optionally a reaction zone, a transport or incubation zone connecting the receiving and reaction zone, respectively, on a substrate, wherein said substrate is a non-porous substrate, and said optional reaction zone and transport or incubation zone consist of areas of projections substantially vertical to said surface, and having a height (H), diameter (D) and reciprocal spacing (t1, t2) such, that lateral capillary flow of said liquid sample in said zones is achieved.

(Fig. 1)

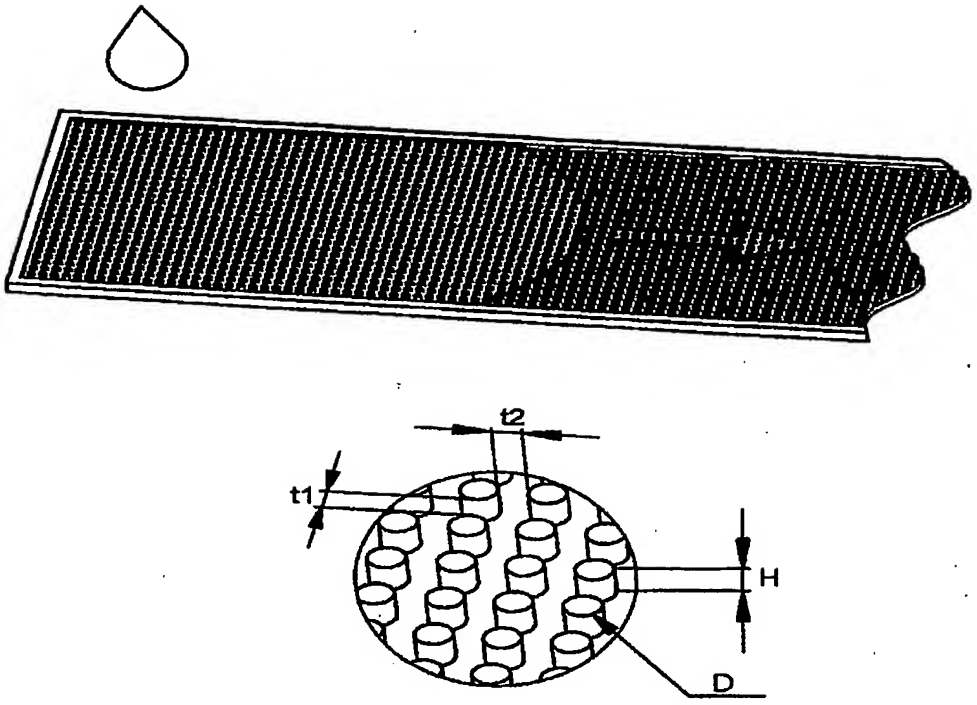

Fig. 1

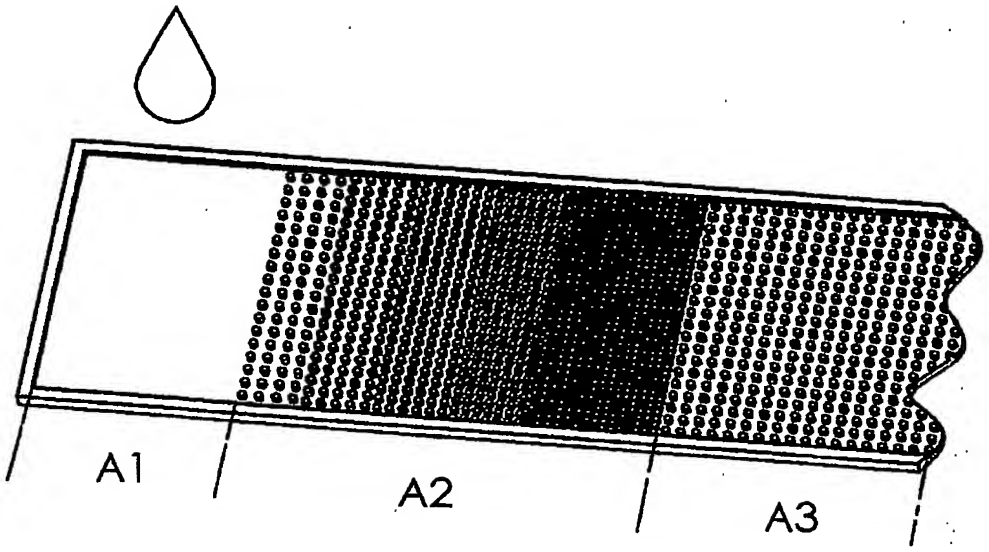

Fig. 2

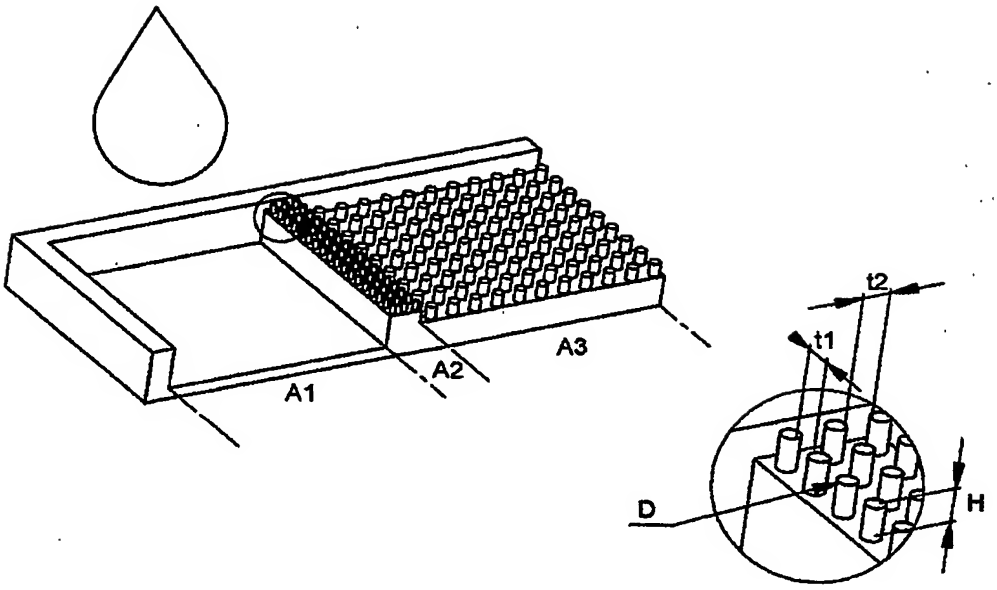

Fig. 3

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/SE05/000429

International filing date: 23 March 2005 (23.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: SE
Number: 0400662-3
Filing date: 24 March 2004 (24.03.2004)

Date of receipt at the International Bureau: 15 April 2005 (15.04.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)